TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys, focus groups, and interviews	300	2	600	1	600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our original request for the information collection was approved January 21, 2020; however, the subsequent public health emergency inhibited our ability to administer the requested survey. We have therefore made no adjustments to our current burden estimate.

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21382 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic User Fee Payment Request Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 1, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0805. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic User Fee Payment Request Forms—Form FDA 3913 and Form FDA 3914

OMB Control Number 0910–0805—Extension

Form FDA 3913, User Fee Payment Refund Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment refund. The information collected includes the organization, contact, and payment information. The information is used to determine the reason for the refund, the refund amount, and who to contact if there are any questions regarding the refund request. A submission of the User Fee Payment Refund Request form does not guarantee that a refund will be issued. FDA estimates an average of 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The estimated hours are based on past FDA experience with the user fee payment refund request.

In fiscal year 2020, approximately 474 user fee refunds were processed for cover sheets and invoices, including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 0 for Export Certificate Program fees, 0 for Freedom of Information Act requests, 31 for Generic Drug User Fees, 200 for Medical Device User Fees, 240 for Medical Device Federal Unified Registration and Listing fees, 0 for Mammography inspection fees, 1 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment transfer request. The information collected includes payment and organization information. The information is used to determine the reason for the transfer, how the transfer should be performed, and who to contact if there are any questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. FDA estimates an average of 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. FDA estimated hours are based on past FDA experience with the user fee payment transfer requests.

In fiscal year 2020, approximately 194 user fee payment transfers were processed for cover sheets and invoices, including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 34 for Generic Drug User Fees, 78 for Medical Device User Fees, 80 for Medical Device Federal Unified Registration and Listing fees, 0 for Mammography inspection fees, 1 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Respondents for the electronic request forms include domestic and foreign firms (including pharmaceutical, biological, medical device firms, etc.). Specifically, refund request forms target respondents who submitted a duplicate payment or overpayment for a user fee cover sheet or invoice. Respondents may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment to be re-applied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms streamline the refund and transfer processes, facilitate processing, and improve the tracking of refund or transfer requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being requested or required has been held to the absolute minimum required for the intended use of the data. Respondents

are able to request a user fee payment refund or transfer online at *https://www.fda.gov/forindustry/userfees/default.htm.* This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

In the **Federal Register** of April 29, 2021 (86 FR 22669), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Payment Refund Request—Form FDA 3913	474	1	474	0.40 (24 minutes)	190
User Fee Payment Transfer Request—Form FDA 3914.	194	1	194	0.25 (15 minutes)	49
Total					239

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The current burden estimate shows a decrease of approximately 642 hours for this information collection over that reported previously. The change reflects increased experience by the respondents to correctly submit fee payments and increased sophistication in use of the forms to request payments made in error. The use of the forms for the user fee programs (*e.g.,* Prescription Drug User Fees, Generic Drug User Fees, Animal Drug User Fees, Animal Generic Drug User Fees, Biosimilar Drug User Fees) are optional.

In addition, new information technology applications have more accurately calculated the number of registrants of drug facilities/food facilities/medical device facilities/medicated feed facilities, and we have therefore revised the number of respondents to the information collection.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21421 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Safety; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 1, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0760. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Safety; Federal-State Food Regulatory Program Standards

OMB Control Number 0910–0760—Revision

This information collection supports implementation of FDA's Federal-State Regulatory Program Standards, part of our National Integrated Food Safety System (IFSS) Programs and Initiatives. For more information we invite you to visit our website at: *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives.* In the United States, Federal and State governments work cooperatively to ensure the safety of food intended for both human and animal consumption. Part of this effort includes developing and maintaining uniform review criteria by which to assess food safety. FDA has established and maintains a number of program standards aimed at improving the safety evaluation for certain food products including manufactured foods and animal feed. Similarly, we are establishing regulatory program standards for eggs and have developed the ''Eggs Regulatory Program Standards'' (ERPS). The ERPS is intended for use by State and local regulatory officials and identifies 10 elements we believe are essential to the effective regulatory assessment of egg safety. States are encouraged to build systems that are sustainable and implement plans corresponding to the IFSS.

In the course of their normal duties, State, local, Territorial, and Tribal governments collect information pertaining to compliance with the respective State, local, Territorial, and Tribal food safety requirements within their jurisdictions. Although content and format of the information collected may vary, these activities are a usual and customary part of routine regulatory oversight. Respondents to the information collection are State, local, Territorial, and Tribal regulatory agencies.

The ERPS offers forms, worksheets, and templates to help respondents assess and meet the program elements identified and discussed. Respondents are not required to use the sample collection instruments included in the ERPS, however all data elements should be submitted to FDA and supporting documentation retained. The ERPS is